An Overview of Requirements for CLIA-Waived Blood Lead Testing Devices in California

All information contained in this document is a summarization and is not intended to be fully representational of the law. For complete details, please contact the appropriate department representative as noted.

Childhood Lead Poisoning Prevention Branch
California Department of Public Health
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Who must report?

Users of Clinical Laboratory Improvement Amendments (CLIA) waived devices are considered "laboratories" and must comply with specific regulations related to reporting, as well as federal certification and state licensing/ registration requirements. A laboratory that performs blood lead analyses ***must*** report all results electronically to the California Department of Public Health (CDPH).

What must be reported?

The result of any blood lead analysis performed on a human blood specimen drawn in the state of California must be electronically reported to CDPH. The information that must be reported includes:

- Patient name, address, date of birth, and demographic information.
- Patient's employer information.
- Ordering health care provider information.
- Blood lead analysis result information.

For exact requirements, please see SECTION 124130 of the CALIFORNIA HEALTH AND SAFETY CODE found here:
http://www.dhs.ca.gov/ohb/olppp/hs124130.pdf

How do I report?

The Childhood Lead Poisoning Prevention Branch (CLPPB) has developed the Online Blood Lead Reporting Form for laboratories to submit blood lead test results to the state. Users simply enter the required information into the form to quickly, easily, and securely transmit blood lead results directly to CDPH. The Online Blood Lead Reporting Form can be accessed from any computer with an internet connection using Microsoft Internet Explorer.

How often do I have to report?

SECTION 124130 of the CALIFORNIA HEALTH AND SAFETY CODE requires:

- Results greater than or equal to 10 µg/dL must be reported within 3 working days of analysis.
- Results less than 10 µg/dL must be reported within 30 calendar days of analysis.

What are the licensing, registration, and certification requirements?

Users of CLIA-waived blood lead analyzing devices must:

- Have a federal Clinical Laboratory Improvement Amendment (CLIA) Certificate of:
  Accreditation ***or*** Compliance ***or*** Provider Performed Microscopy Procedures ***or*** Waiver.
- Be registered or licensed with the State of California, Laboratory Field Services (LFS).

For questions related to federal CLIA certification, state registration or licensing, please contact:
Laboratory Field Services (510) 620-3800

If your laboratory will be performing blood lead testing for the purposes of monitoring occupational exposure, your laboratory must appear on the Occupational Safety and Health Administration (OSHA) List of Laboratories Approved for Blood Lead Analysis. Employers who do blood lead testing under OSHA lead standards are required to use laboratories that appear on this list.

For OSHA list information, contact:
Jim Pike (801) 233-4927
pike.jim@dol.gov

For occupational lead testing information, contact:
Susan Payne (510) 620-5733
susan.payne@cdph.ca.gov

Does the State offer a reimbursement program?

Yes! The California Child Health and Disability Program (CHDP) offers reimbursement for the analytic phase of blood lead testing. To qualify for CHDP reimbursement, your clinic must comply with the certification, state licensing or registration, and reporting requirements as described above, ***and must also***:

- Be enrolled in and be rated as proficient in the California Blood Lead Proficiency Assurance Program administered by CDPH Environmental Health Laboratory Branch.
- Be enrolled in the CHDP program as outlined in the CHDP Provider Manual found here:
  http://www.medi-cal.ca.gov/
- Submit claims and documentation on the CONFIDENTIAL SCREENING/BILLING REPORT (PM 160) form.

For further information regarding the CHDP reimbursement program, please contact:
Mary Fowler (510) 620-2879
mary.fowler@cdph.ca.gov

Getting started is as easy as 1, 2, 3...

Day 1 - Receive and review the CALIFORNIA ELECTRONIC BLOOD LEAD REPORTING SYSTEM: REQUIREMENTS AND PROCEDURES manual provided by CLPPB.

Day 2 - Schedule an Online Blood Lead Reporting Form training session that will familiarize you with the data entry and submittal steps as part of the electronic blood lead reporting process. To schedule an appointment, contact:

Mario Amanzio (510) 620-5653
mario.amanzio@cdph.ca.gov

or

Anna Malinis (510) 620-5652
anna.malinis@cdph.ca.gov

Day 3 - Receive the 20-minute Online Blood Lead Reporting Form training session by telephone. You will need access to a computer with an internet connection and Microsoft Internet Explorer. Upon approval from CLPPB, your laboratory may begin electronic blood lead reporting!